EXHIBIT 31

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 20 1995

Amide Pharmaceuticals
101 East Main Street
Little Falls, New Jersey 07424
Attention: Mr. Jasmine Shah
Director, Regulatory Affairs

Dear Mr. Shah:

We are pleased to inform you that we are exempting you from the batch-by-batch certification process as described in Title 21 Code of Federal Regulations (21 CFR) Section 310.500 Digoxin Products for oral use; conditions for marketing. This exemption applies to batches of Digoxin Tablets 0.125mg, 0.25mg, and 0.5mg potencies produced at your Little Falls, NJ, establishment subsequent the production of the batches certified by our letter of June 8, 1995.

The agency reserves the right to revoke this exemption.

Please contact FDA's Division of Drug Analysis (DDA), St. Louis, MO, (314) 539-2134, FAX (314) 539-2113, within the next 30 days for the return of any Digoxin Tablet samples previously submitted for certification testing. Samples not requested to be returned will be disposed of by the lab without further notice, 60 days after the date of this letter.

Sincerely yours,

John P. Loh
Branch Chief
Product Surveillance Branch, HFD-333
Division of Drug Quality Evaluation
Office of Compliance
Center for Drug Evaluation and Research

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